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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/871,607	05/31/2001	Timur Yarovinsky	UIA-031.01	1145

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EXAMINER
MYERS, CARLA J

ART UNIT PAPER NUMBER

1634

DATE MAILED: 01/15/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/871,607

Applicant(s)

YAROVINSKY, TIMUR

Examiner

Carla Myers

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(p).

Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 11-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7, 2
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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1. Applicant's election without traverse of group I, claims 1-10 in Paper No. 11 is acknowledged.
2. The specification is objected to because the assigned SEQ ID NOs have not been used to identify each sequence listed, as required under 37 CFR §1.821(d). See for example, page 13 of the specification and the description of the figure 1, which contains nucleic acid sequences.
3. Claims 1, 3-5 and 7-10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to nucleic acids and adaptors comprising a scissile strand topoisomerase I cleavage motif. The specification teaches 2 examples of a scissile strand topoisomerase motif, namely CCCTT and TCCTT. Accordingly, the claimed nucleic acids and adaptors comprising the topoisomerase motifs CCCTT and TCCTT meet the written description requirements of 35 U.S.C. 112, first paragraph. However, the claims as broadly written include a topoisomerase I cleavage motif from any prokaryotic or eukaryotic organism. It is noted that the prior art has characterized additional topoisomerase motifs. For example, Edwards (page 2573) teaches that SV40 DNA contains 68 sites at which procaryotic topoisomerase I cleaves DNA and states that a consensus sequence for topoisomerase I appears to occur every 6-7 nucleotides within the DNA of SV40. However, the genus of motifs claimed is significantly large and the majority of topoisomerase I motifs have not been sufficiently defined in terms of their structure.

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In *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA... requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention". In analyzing whether the written description requirement is met for a genus claim, it is first determined whether a representative number of species have been described by their complete structure. In the instant case, only 2 members of the genus of topoisomerase motifs that can be cleaved and rejoined by a topoisomerase I enzyme have been disclosed. The specification discloses only one enzyme, vaccinia virus topoisomerase I which is able to catalyze both the specific cleavage and subsequent joining of sequences that have the topoisomerase cleavage motif of (C/T)CCTT. It is then determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics (e.g. restriction map, chromosomal map position, biological activity of an encoded protein product, etc.). In the instant case, no such identifying characteristics have been provided for any of the claimed nucleic acids or adaptors. *Vas-Cath Inc. V. Mahurkar*, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable

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clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed". Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision. For the reasons stated above, Applicants have not provided sufficient evidence that they were in possession, at the time of filing, of the invention as it is broadly claimed and thus the written description requirement has not been satisfied for the claims as they are broadly written. Applicants attention is drawn to the Guidelines for the Examination of Patent Applications under 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

4. Claims 1, 3-5, and 7-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 3-5, and 7-10 are indefinite and vague over the recitation of a topoisomerase I cleavage motif because it is unclear as to what is intended to be encompassed by this sequence. It is unclear as to whether this sequence is intended to include, for example, only the sequences 5' or 3' of the cleavage site. It is also unclear as to whether the topoisomerase cleavage I motif includes the full length sequence recognized by a topoisomerase or includes only a portion of those sequences. For example, it is unclear as to whether CCTT would constitute a

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topoisomerase cleavage motif and it is unclear as to what length of sequence is required in order for a sequence to be considered a topoisomerase I cleavage motif.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Cheng (reference

"C1").

Cheng (page 11591) teaches a labeled nucleic acid consisting of:

5'-CGTGTGCGCCCTTATTCCTT-3'. This nucleic acid comprises a topoisomerase I cleavage motif (i.e., CCCTT) which is not more than 10 bases from the 3' end of the nucleic acid.

Additionally, the sequences 5' of the CCCTT meet the limitations of claim 3 in that they constitutes a mutational sequence, a polypeptide tag encoding sequence, a nucleic acid tag sequence, a terminator sequence, a fusible protein encoding sequence, a radioactively labeled nucleotide sequence, a chemically labeled nucleotide sequence and a sequence that is within some intron sequence.

6. Claims 4-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Hudson (GenBank Accession No. G06435).

Hudson teaches a nucleic acid which comprises each of the nucleotide sequences required by claims 4-10. In particular, the nucleic acid of Hudson comprises: a) a topoisomerase I

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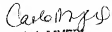
cleavage site having a 5' end consisting of TCCT and a 3' end consisting of "T", a palindrome of 2 nucleotides, GC, 3' to the 3' terminus of the topoisomerase I cleavage site, and an "A" nucleotide complementary to the 3' nucleotide of the topoisomerase I cleavage site (see nucleotides 229-237); b) a GATC Sau3A I restriction endonuclease site (see nucleotides 117-120); c) an AGCT sequence that is complementary to a 5' overhang sequence of a Sal I cleavage site (see nucleotides 23-26); d) an AGGA sequence complementary to the 5' end of the topoisomerase I cleavage site (see nucleotides 29-32 and 187-190); and e) a sequence 5' of the topoisomerase I cleavage site which contains nucleotides which have the ability to function as a mutational sequence, a polypeptide tag encoding sequence, a nucleic acid tag sequence, a terminator sequence, a fusible protein encoding sequence, and a sequence that is within some intron sequence.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (703) 308-2199. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703)-308-1152. Papers related to this application may be faxed to Group 1634 via the PTO Fax Center using the fax number (703)-872-9306 or (703)-872-9307 (after final).

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Carla Myers
January 13, 2002


CARLA J. MYERS
PRIMARY EXAMINER